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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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Todd Robida

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EXAMINER

BOECKMANN, JASON J

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PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/801,307	<b>Applicant(s)</b> ROBIDA, TODD	
	<b>Examiner</b> Jason J. Boeckmann	<b>Art Unit</b> 3752	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 16 August 2010.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-20 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-20 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 16 August 2010 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                     | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____                                      |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)          | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____  | 6) <input type="checkbox"/> Other: _____                          |

## **DETAILED ACTION**

### ***Continued Examination Under 37 CFR 1.114***

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 8/16/2010 has been entered.

### ***Drawings***

The drawings were received on 8/16/2010. These drawings are acceptable. It is noted that new figure 18a and figures 18b and c have now been entered.

### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-7 and 11-20 are rejected, as best as understood, under 35 U.S.C. 103(a) as being unpatentable over the applicant's admitted prior art of figure 1 (everything but the valve 70), in view of Kintner (3,426,799).

The applicants admitted prior art discloses a medical device coating unit comprising a three-way valve (70), a solution reservoir (11) connected to a first port, a solution receptacle (14) connected to a second port, and a solution outlet (12) connected to a third port. The medical device being adapted to withdraw the coating solution from the reservoir (11) through the valve (70) and into the solution receptacle (14) and expel the coating material from the solution receptacle (14) through the valve (70) and through the solution outlet (12). The admitted prior art does not specifically disclose that the valve is a pneumatically actuated three-way valve with no spring return mechanism and two valve seats.

However, Kintner shows a pneumatic actuated valve (figures 1 and 2) and a three-way valve (figure 3), both having no spring return mechanism. The three way valve comprising first (22), second (23) and third (24) valve ports, and the pneumatic actuated valves include two pneumatic ports (8 and 6), two air pressure diaphragms (the rubber seal on the top of elements 10 and 12), and two valve seats (any two of 13, 14 and 15).

It would have been obvious to one of ordinary skill in the art at the time of the applicant's invention to combine the teachings of figures 1 and 2 of Kitner with the teaching of figure 3 in order provide a pneumatically actuated three-way valve, and substitute the new pneumatically actuated three-way valve of Kintner for the three-way

valve of figure 1 in order to make the medical device operate more precisely by having a pneumatic return mechanism that can be adjusted.

Regarding claims 2 and 11, as well as understood, the three-way valve of Kintner comprises a position in which all valve seats remain open (see figure 3).

Regarding claims 3, 4, 12 and 13, the solution receptacle comprises a syringe (14) and the solution outlet comprises a spray nozzle (12).

Regarding claim 6, it is inherent that there is a supply pressure source in the device of the applicant's admitted prior art as modified by Kintner, however, one of ordinary skill in the art at the time of the applicant's invention would be able to supply a pressure source, to the medical device of the admitted prior art as modified by Kintner, that provides a pressure within a range of about 300 kilo-Pascals to about 500 kilo-Pascals in order to move the valve from the first position to the second position more accurately.

Regarding claim 7, the medical device of the admitted prior art as modified by Kintner includes a first tube (13a) having a first diameter coupled to the first port (8) and a second tube (13c) having a second diameter coupled to the second port (6).

Regarding claim 10, the medical device of the admitted prior art as modified by Kintner includes one or more disposable fittings (16a, 16b, 16c, 16d of the admitted prior art).

Regarding claims 14-20, in its use, the device of the applicants admitted prior art, as modified by Kintner, will inherently perform the method steps of claims 14-20.

Claims 1-4, 6, 7 and 10-20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Liston (3,817,425) in view of Kintner (3,426,799).

Liston discloses a medical device coating unit comprising a three-way valve (300), a solution reservoir (272) connected to a first port (305), a solution receptacle (291) connected to a second port (307), and a solution outlet (226) connected to a third port (306). The medical device being adapted to withdraw the coating solution from the reservoir (272) through the valve (300) and into the solution receptacle (291) and expel the coating material from the solution receptacle (291) through the valve (300) and through the solution outlet (226). Liston does not specifically disclose that the valve is a pneumatic actuated three-way valve with no spring return mechanism and two valve seats.

However, Kintner shows a pneumatic actuated valve (figures 1 and 2) and a three-way valve (figure 3), both having no spring return mechanism. The three way valve comprising first (22), second (23) and third (24) valve ports, and the pneumatic actuated valves include two pneumatic ports (8 and 6), two air pressure diaphragms (the rubber seal on the top of elements 10 and 12), and two valve seats (any two of 13, 14 and 15).

It would have been obvious to one of ordinary skill in the art at the time of the applicant's invention to combine the teachings of figures 1 and 2 of Kitner with the teaching of figure 3 in order provide a pneumatically actuated three-way valve, and substitute the new pneumatic actuated three-way valve of Kintner for the three-way

valve of Liston in order to make the medical device operate more precisely by having a pneumatic return mechanism that can be adjusted.

Regarding claims 2 and 11, the three-way valve of Kintner comprises a position in which all valve seats remain open (see figure 3).

Regarding claims 3, 4, 12 and 13, the solution receptacle comprises a syringe (291) and the solution outlet comprises a spray nozzle (226).

Regarding claim 6, it is inherent that there is a supply pressure source in the device of the Liston as modified by Kintner, however, one of ordinary skill in the art at the time of the applicant's invention would be able to supply a pressure source, to the medical device of the admitted prior art as modified by Kintner, that provides a pressure within a range of about 300 kilo-Pascals to about 500 kilo-Pascals in order to move the valve from the first position to the second position more accurately.

Regarding claim 7, the medical device of Liston as modified by Kintner includes a first tube (275) having a first diameter coupled to the first port (305) and a second tube (298) having a second diameter coupled to the second port (307).

Regarding claims 14-20, in its use, the device of Liston, as modified by Kintner, will inherently perform the method steps of claims 14-20.

Claims 1-7 and 10-20 are rejected under 35 U.S.C. 103(a) as being unpatentable the applicant's admitted prior art of figure 1-8 (including valve 70), in view of Kintner (3,426,799).

The applicants admitted prior art discloses a medical device coating unit comprising a three-way valve (20 the prior art valve with the spring return mechanism), a solution reservoir (11) connected to a first port, a solution receptacle (14) connected to a second port, and a solution outlet (12) connected to a third port. The medical device being adapted to withdraw the coating solution from the reservoir (11) through the valve (70) and into the solution receptacle (14) and expel the coating material from the solution receptacle (14) through the valve (70) and through the solution outlet (12), the three way valve comprising two valve seats and an air pressure diaphragm. The admitted prior art does not specifically disclose that the valve is a pneumatically actuated three-way valve comprising two air pressure diaphragms and with no spring return mechanism.

However, Kintner shows a pneumatic actuated valve that has a pneumatic port on one end, to move the valve assembly to the open position, and either a spring return mechanism (figures 4 and 5) or another pneumatic port on the other end (figure 4), to move the valve assembly to the closed position, therefore, Kintner teaches that a pneumatic port can be interchangeable with a return spring mechanism.

It would have been obvious to one of ordinary skill in the art at the time of the applicant's invention to replace the spring return mechanism of the admitted prior art valve with a pneumatic port, including an air pressure diaphragm, in order to move the valve assembly in the opposite direction as the already existing pneumatic port and air pressure diaphragm, as taught by Kintner. This modification would give the valve more accuracy in positioning the valve assembly between the two valve seats.



Regarding claims 6 and 20, it is inherent that there is a supply pressure source in the device of the applicant's admitted prior art as modified by Kintner, however, one of ordinary skill in the art at the time of the applicant's invention would be able to supply a pressure source, to the medical device of the admitted prior art as modified by Kintner, that provides a pressure within a range of about 300 kilo-Pascals to about 500 kilo-Pascals in order to move the valve from the first position to the second position more accurately.

Regarding claims 2 and 11, as well as understood, the three-way valve of Kintner comprises a position in which all valve seats remain open (see figure 3).

Regarding claims 3, 4, 12 and 13, the solution receptacle comprises a syringe (14) and the solution outlet comprises a spray nozzle (12).

Regarding claim 6, each of the pneumatic ports inherently includes a supply pressure source that is capable of supplying a pressure within the claimed range.

Regarding claim 7, the medical device of the admitted prior art as modified by Kintner includes a first tube (13a) having a first diameter coupled to the first port (8) and a second tube (13c) having a second diameter coupled to the second port (6).

Regarding claim 10, the medical device of the admitted prior art as modified by Kintner includes one or more disposable fittings (16a, 16b, 16c, 16d of the admitted prior art).

Regarding claims 14-20, in its use, the device of the applicants admitted prior art, as modified by Kintner, will inherently perform the method steps of claims 14-20.

Claims 8 and 9 are rejected under 35 U.S.C. 103(a) as being unpatentable over the applicant's admitted prior art (figures 1-8), in view of Kintner (3,426,799) further in view of Chemline Plastics Ltd. (2001).

The applicant's admitted prior art as modified by Kintner shows all aspects of the applicant's invention as in claim 5, including threaded inserts (14, 15, 16), but does not specifically disclose that it contains stainless steel threaded inserts.

However, Chemline Plastics Ltd. shows a pneumatic valve with stainless steel threaded inserts (page 2).

It would have been obvious to one of ordinary skill in the art at the time of the applicant's invention to substitute the stainless steel threaded inserts of Chemline Ltd. for the threaded inserts of the applicant's admitted prior art as modified by Brown, in order to prevent corrosion.

Additionally, it is well known that stainless steel is an obvious choice of material for medical devices due to its ability to resist corrosion and be easily cleaned.

Therefore, it would have been obvious to one of ordinary skill in the art at the time of the applicant's invention to make the valve body out of stainless steel in order to prevent corrosion.

In addition, It would have been obvious to one of ordinary skill in the art at the time of the applicant's invention to make the valve body out of stainless steel along with the threaded inserts, since it has been held to be within the general skill of a worker in the art to select a known material on the basis of its suitability for the intended use as a matter of design choice (In re Leshin, 125 USPQ 416).

### ***Response to Arguments***

Applicant's arguments filed 8/16/2010 have been fully considered but they are not persuasive.

Since the applicant has not provided any new arguments, please see the examiner's previously presented arguments.

Regarding the applicants remarks concerning the 112 first paragraph rejections, it is noted that there is no enablement rejection, only a new matter rejection. Please see rejection above.

Regarding the applicants remarks towards the Kitner reference, Kitner discloses multiple embodiments including dual pneumatically actuated valves, three way valves and spring return valves. Kitner discloses a multiple valves with multiple means form operation, the rejection merely combines the three way valve of figure 3 with the means for operation shown in figures 1 and 2. The dual actuated valves comprising valve seats (any two of the three 13, 14 and 15) and air pressure diaphragms (the rubber elements on the outside of members 10 and 12). The air pressure diaphragms and valve seats of Kitner are air pressure diaphragms and valve seats to the same extent that the present invention has air pressure diaphragms and valve seats. Specifically, it appears form the figures that the air pressure diaphragm 78 is mounted on the piston 77 (or plunger) just as the air pressure diaphragm of Kitner is mounted on the piston 30 (or plunger). Additionally, figure 4 and 5 of Kitner are not being used to teach a three way valve as

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shown in figure 3, but are used to disclose that a dual actuated pneumatic valve is interchangeable with a single pneumatic/spring return valve, see the rejection above. Additionally it is noted that the applicant argues that the modified valve would not have a default neutral state in which all valve seats remain open. However the valve of Kitner does include a position that has all seats open (figure 3). It is noted that nowhere in the claim is the valve required to return to the default neutral state without any type of force being applied thereto. The valve of Kitner includes a default neutral state in which all valve seats are open.

Additionally, it is noted that the applicant fails to address the second 103 rejection of the applicants admitted prior art figures 1-8, (including the valve 70) in view of Kitner. In this rejection the examiner is merely modify the admitted prior art valve with the teachings of Kitner. Since the applicant has not responded to this rejection, the examiner is under the impression that this is an acceptable rejection on the merits in the eye of the applicant.

### ***Conclusion***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jason J. Boeckmann whose telephone number is (571)272-2708. The examiner can normally be reached on 8:00- 5:00, Monday through Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Len Tran can be reached on (571) 272-1184. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Jason J Boeckmann/  
Examiner, Art Unit 3752  
9/17/2010